

### **REMARKS**

Claims 1-5, 7-10 and 18-35 are pending in the application. Of these, Claims 1-5, 7-10 and 18-27 are allowed. Support for amendments to Claims 28-31 is found in the Specification as filed, for example at page 8, 2<sup>nd</sup> full paragraph. No new matter has been added herewith. The following addresses the substance of the Office Action.

#### **Enablement**

Claims 28-35 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for antibody fragments selected from the group consisting of Fab, F(ab)<sub>2</sub> and Fv, does not reasonably provide enablement for fragments consisting of a single CDR, wherein the fragment retains antigen-binding specificity. The Examiner notes that the formation of an intact antigen-binding site generally requires the association of the complete heavy chain and light chain variable regions of a given antibody, each of which consists of three CDRs, which provide the majority of the contact residues for the binding of the antibody to its target epitope. Claims 28-35 were interpreted by the Examiner to refer to an antibody fragment consisting of a single CDR, wherein the fragment retains antigen-binding specificity. Thus, the claims were rejected for failure to teach how to make and or use such antibodies.

Recitation of CDR in Claims 28-35 was intended to mean “complementarity-determining region”. As the Examiner pointed out, a complementary determining region is known to consist of three sub-regions (i.e., CDR1, CDR2 and CDR3). To explicitly include all of the sub-regions, Claims 28-31 are amended to recite “complementary-determining regions (CDRs)”, which one of skill in the art would interpret as referring to the three sub-regions collectively. Moreover, the claims stipulate that said fragment retains antigen-binding specificity of said antibody. As the Examiner has indicated, only fragments that contain the complete CDR (with CDR1, CDR2 and CDR3) would be expected to retain antigen-binding specificity.

In view of these amendments, the Applicants respectfully request removal of the rejection.

#### No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

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any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

### CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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